U.S. Environmental Protection Agency

Integrated Risk Information System

1,2-Dichloroethane (CASRN 107-06-2)

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1,2-Dichloroethane; CASRN 107-06-2

Health assessment information on a chemical substance is included in IRIS only after a comprehensive review of chronic toxicity data by U.S. EPA health scientists from several Program Offices and the Office of Research and Development. The summaries presented in Sections I and II represent a consensus reached in the review process. Background information and explanations of the methods used to derive the values given in IRIS are provided in the Background Documents.

STATUS OF DATA FOR 1,2-Dichloroethane

File First On-Line 03/31/1987

Category (section)	Status	Last Revised
Oral RfD Assessment (I.A.)	no data	
Inhalation RfC Assessment (I.B.)	no data	
Carcinogenicity Assessment (II.)	on-line	01/01/1991

_I. Chronic Health Hazard Assessments for Noncarcinogenic Effects

_I.A. Reference Dose for Chronic Oral Exposure (RfD)

Substance Name -- 1,2-Dichloroethane
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Not available at this time.

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_I.B. Reference Concentration for Chronic Inhalation Exposure (RfC)

Substance Name -- 1,2-Dichloroethane
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Not available at this time.

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_II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name -- 1,2-Dichloroethane
CASRN -- 107-06-2
Last Revised -- 01/01/1991

Section II provides information on three aspects of the carcinogenic assessment for the substance in question; the weight-of-evidence judgment of the likelihood that the substance is a human carcinogen, and quantitative estimates of risk from oral exposure and from inhalation exposure. The quantitative risk estimates are presented in three ways. The slope factor is the result of application of a low-dose extrapolation procedure and is presented as the risk per (mg/kg)/day. The unit risk is the quantitative estimate in terms of either risk per ug/L drinking water or risk per ug/cu.m air breathed. The third form in which risk is presented is a drinking water or air concentration providing cancer risks of 1 in 10,000, 1 in 100,000 or 1 in 1,000,000. The rationale and methods used to develop the carcinogenicity information in IRIS are described in The Risk Assessment Guidelines of 1986 (EPA/600/8-87/045) and in the IRIS Background Document. IRIS summaries developed since the publication of EPA's more recent Proposed Guidelines for Carcinogen Risk Assessment also utilize those Guidelines where indicated (Federal Register 61(79):17960-18011, April 23, 1996). Users are referred to Section I of this IRIS file for information on long-term toxic effects other than carcinogenicity.

_II.A. Evidence for Human Carcinogenicity

__II.A.1. Weight-of-Evidence Characterization

Classification -- B2; probable human carcinogen

Basis -- Based on the induction of several tumor types in rats and mice treated by gavage and lung papillomas in mice after topical application

__II.A.2. Human Carcinogenicity Data

None.

__II.A.3. Animal Carcinogenicity Data

1,2-Dichloroethane in corn oil was administered by gavage to groups of 50 each male and female Osborne-Mendel rats and B6C3F1 mice. Treatment was for 78 weeks followed by an additional observation period of 12-13 weeks for mice or 32 weeks for low-dose rats. TWA dosages were 47 and 95 mg/kg/day for rats, 97 and 195 mg/kg/day for male mice and 149 and 299 mg/kg/day for female mice. All high-dose male rats died after 23 weeks of observation; the last high-dose female died after 15 weeks. Male rats had significantly increased incidence of forestomach squamous-cell carcinomas and circulatory system hemangiosarcomas. Female rats and mice were observed to have significant increases in mammary adenocarcinoma incidence. Mice of both sexes developed alveolar/bronchiolar adenomas, females

Quantitative Estimate of Carcinogenic Risk from Oral Exposure

- Summary of Risk Estimates
- Dose-Response Data
- Additional Comments
- Discussion of Confidence

Quantitative Estimate of Carcinogenic Risk from Inhalation Exposure

- Summary of Risk Estimates
- Dose-Response Data
- Additional Comments
- Discussion of Confidence

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developed endometrial stromal polyps and sarcomas, and males developed hepatocellular carcinomas (NCI, 1978).

Inhalation exposure of Wistar, Sprague-Dawley rats and Swiss mice did not result in increased tumor incidence (Spencer et al., 1951; Maltoni et al., 1980). An elevation that was not statistically significant in lung adenomas was seen in A/st mice treated i.p. with 1,2-dichloroethane in tricaprylin (Theiss et al., 1977). ICR/Ha Swiss mice treated topically had a significant increase in benign lung papillomas, but not skin carcinomas (van Duuren et al., 1979).

__II.A.4. Supporting Data for Carcinogenicity

1,2-Dichloroethane was mutagenic for Salmonella in assays wherein excessive evaporation was prevented; exogenous metabolism by mammalian systems enhanced the response (Nestmann et al., 1980; Barber et al., 1981; Rannug et al., 1978). Both somatic cell mutations and sex-linked recessives were induced in Drosphila (Nylander et al., 1979; Shakarnis, 1969, 1970; King et al., 1979). Metabolites of 1,2-dichloroethane have been shown to form adducts with DNA after in vitro or in vivo exposures.

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_II.B. Quantitative Estimate of Carcinogenic Risk from Oral Exposure

__II.B.1. Summary of Risk Estimates

Oral Slope Factor -- 9.1E-2 per (mg/kg)/day

Drinking Water Unit Risk -- 2.6E-6 per (ug/L)

Extrapolation Method -- : Linearized multistage procedure with time-to-death analysis, extra risk

Drinking Water Concentrations at Specified Risk Levels:

Risk Level	Concentration
E-4 (1 in 10,000)	4E+1 ug/L
E-5 (1 in 100,000)	4E+0 ug/L
E-6 (1 in 1,000,000)	4E-1 ug/L

__II.B.2. Dose-Response Data (Carcinogenicity, Oral Exposure)

Tumor Type: hemangiosarcomas
Test animals: rat/Osborne-Mendel, male
Route: gavage
Reference: NCI, 1978

Administered Dose (mg/kg/day)	Human Equivalent Dose (mg/kg/day)	Tumor Incidence
0	0	0/40
47	4.46	9/48
95	8.23	7/27

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__II.B.3. Additional Comments (Carcinogenicity, Oral Exposure)

Equivalent human dose was calculated using an assumed 70-kg human weight and the reported terminal rat weight of 0.5 kg. Metabolism of 1,2- dichloroethane after oral exposure is dose-dependent. Metabolism was estimated to be <50% saturation at the dose equal to the TWA for rats but near saturation for the high-dose mice in the NCI (1978) bioassay. Because of the high mortality rate in the high-dose rats, a time-to-event analysis was used to quantitate the risk estimate. It was assumed that rats with hemangiosarcomas were killed by the tumors. The 95% upper bound of the risk was calculated using 90 weeks to approximate the lifetime risk.

The unit risk should not be used if the water concentration exceeds 4E+3 ug/L, since above this concentration the unit risk may not be appropriate.

__II.B.4. Discussion of Confidence (Carcinogenicity, Oral Exposure)

Adequate numbers of animals were treated and observed for the majority of their expected lifespan. The incidence of hemangiosarcoma was significantly elevated in the treated animals and was dose-related. A slope factor of 6.2E-2 (mg/kg)/day, calculated from data on hepatocellular carcinomas in male mice (NCI, 1978), is supportive of the risk estimate.

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_II.C. Quantitative Estimate of Carcinogenic Risk from Inhalation Exposure

__II.C.1. Summary of Risk Estimates

Inhalation Unit Risk -- 2.6E-5 per (ug/cu.m)

Extrapolation Method -- Linearized multistage procedure, extra risk

Air Concentrations at Specified Risk Levels:

Risk Level	Concentration
E-4 (1 in 10,000)	4E+0 ug/cu.m
E-5 (1 in 100,000)	4E-1 ug/cu.m
E-6 (1 in 1,000,000)	4E-2 ug/cu.m

__II.C.2. Dose-Response Data for Carcinogenicity, Inhalation Exposure

The inhalation unit risk was calculated from oral data in Section II.B.2., assuming 100% absorption and metabolism at the low dose.

__II.C.3. Additional Comments (Carcinogenicity, Inhalation Exposure)

Reitz et al. (1982) found the major urinary metabolites in rats of ingested and inhaled 1,2-dichloroethane to be identical and generated in the same relative amounts.

The unit risk should not be used if the air concentration exceeds 4E+2 ug/cu.m, since above this concentration the unit risk may not be appropriate.

__II.C.4. Discussion of Confidence (Carcinogenicity, Inhalation Exposure)

This inhalation risk estimate was derived from the oral data presented in Section II.B.2. Based on the negative inhalation study of Maltoni et al. (1980), a 95% upper bound on risk was inferred to be 1.0E-6 per (ug/cu.m) approximately 26 times smaller than in the unit risk calculated from the rat gavage data.

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_II.D. EPA Documentation, Review, and Contacts (Carcinogenicity Assessment)

__II.D.1. EPA Documentation

Source Document -- U.S. EPA, 1985

The Health Assessment Document for 1,2-Dichloroethane received both Agency and external review.

__II.D.2. EPA Review (Carcinogenicity Assessment)

Agency Work Group Review -- 12/04/1986

Verification Date -- 12/04/1986

__II.D.3. EPA Contacts (Carcinogenicity Assessment)

Please contact the IRIS Hotline for all questions concerning this assessment or IRIS, in general, at (202)566-1676 (phone), (202)566-1749 (FAX) or hotline.iris@epa.gov (internet address).

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_III. [reserved]
_IV. [reserved]
_V. [reserved]

_VI. Bibliography

Substance Name -- 1,2-Dichloroethane
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_VI.A. Oral RfD References

None

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_VI.B. Inhalation RfC References

None

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_VI.C. Carcinogenicity Assessment References

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pulmonary tumor response in strain A mice. Cancer Res. 37: 2717.

U.S. EPA. 1985. Health Assessment Document for 1,2-Dichloroethane. Prepared by the Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, Research Triangle Park, NC. EPA 600/8-84-006F.

van Duuren, B., B. Goldschmidt, G. Loewengart, et al. 1979. Carcinogenicity of halogenated olefinic and aliphatic hydrocarbons in mice. J. Natl. Cancer Inst. 63: 1433-1439.

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_VII. Revision History

Substance Name -- 1,2-Dichloroethane
CASRN -- 107-06-2

Date	Section	Description
03/01/1988	II.B.4.	Confidence statement revised
03/01/1988	II.C.2.	Text added
03/01/1988	II.C.4.	Confidence statement revised
03/01/1988	III.A.	Health Advisory added
05/01/1989	IV.C.2.	All values corrected
08/01/1989	VI.	Bibliography on-line
03/01/1990	II.A.3.	Text revised (second paragraph)
06/01/1990	IV.A.1.	Area code for EPA contact corrected
06/01/1990	IV.F.1.	EPA contact changed
01/01/1991	II.	Text edited
01/01/1991	II.C.1.	Inhalation slope factor removed (global change)
01/01/1992	IV.	Regulatory actions updated
04/01/1992	IV.A.1.	CAA regulatory action withdrawn
07/01/1992	SYNONYMS	Synonyms corrected
07/01/1993	VI.C.	References alphabetized correctly
04/01/1997	III., IV., V.	Drinking Water Health Advisories, EPA Regulatory Actions, and Supplementary Data were removed from IRIS on or before April 1997. IRIS users were directed to the appropriate EPA Program Offices for this information.
01/12/2000	I., II.	This chemical is being reassessed under the IRIS Program.

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_VIII. Synonyms

Substance Name -- 1,2-Dichloroethane
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Last Revised -- 07/01/1993

107-06-2
Ethane, 1,2-dichloro-
Ethylene Dichloride
1,2-DICHLOROETHANE
Dichloroethane, 1,2-
Aethylenchlorid [German]
AI3-01656
alpha,beta-DICHLOROETHANE
BICHLORURE D'ETHYLENE [French]
BORER SOL
Brocide
Caswell No. 440
CCRIS 225
CHLORURE D'ETHYLENE [French]
CLORURO DI ETHENE [Italian]
DESTRUXOL BORER-SOL
DI-CHLOR-MULSION
Dichlor-Mulsion
Dichloremulsion
DICHLORO-1,2-ETHANE [French]
Dichlorure d'ethylene [French]
Dicloruro de etileno [Spanish]
DUTCH LIQUID
DUTCH OIL
EDC
ENT 1,656
EPA Pesticide Chemical Code 042003
Ethane dichloride
Ethane, 1,2-Dichloro-
Ethyleendichloride [Dutch]
Ethylene chloride
Glycol dichloride
HSDB 65
NCI-C00511
RCRA WASTE NUMBER U077
sym-DICHLOROETHANE
1,2-BICHLOROETHANE
1,2-DCE
1,2-DICHLOORETHAAN [Dutch]
1,2-DICHLOR-AETHAN [German]
1,2-DICHLORETHANE
1,2-DICLOROETANO [Italian]
1,2-ETHYLENE DICHLORIDE

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